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INTELLECTUAL PROPERTY LAW

IFW

August 15, 2006

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Our Reference: 10935-35

INFORMATION DISCLOSURE STATEMENT

The Commissioner of Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Re: **United States Patent Application No. 10/596,479**
Filed: June 14, 2006
For: METHOD OF TREATING ELEVATED PLASMA HOMOCYSTEINE LEVELS IN ESRD PATIENTS
Applicant: Bradley L. Urquhart et al.

In accordance with 37 CFR 1.97 and 1.98, and in recognition of the duty of disclosure set forth in 37 CFR 1.56, Applicants hereby submit an Information Disclosure Statement on Form PTO-1449 containing a listing of patents and other publications of which Applicant is aware. Applicants are also submitting the references listed on the Supplemental Information Disclosure Statement.

All of the patents and publications submitted herewith are in the English language. Accordingly a concise explanation of the relevance of the documents is not required.

The Examiner is requested to indicate consideration of these documents by initialing the appropriate column.

Applicants reserve the right to contest the applicability of any of these documents as prior art against the subject application. If the Examiner has any questions concerning this Information Disclosure Statement, he/she is requested to contact the undersigned. Entry of the enclosed Information Disclosure Statement is believed to be in order and is respectfully requested.

This Information Disclosure Statement is being filed before the issuance of a first official action, and therefore no fees are required. However, please charge our deposit account No. 02-2095 if such a fee is required.

Respectfully submitted,

BRADLEY L. URQUHART

Patricia Folkins
Registration No. 51,379
Dated: August 15, 2006

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PTO/SB/21 (09-04)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	5

Application Number	10/596,479
Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart et al.
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	10935-35

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Bereskin & Parr		
Signature	P. Folkins		
Printed Name	Patricia Folkins		
Date	August 15, 2006	Reg. No.	51,379

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Sheet 1 of 3

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Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.	FINKELSTEIN, J. D., "The metabolism of homocysteine: pathways and regulation", Eur J Pediatr, 1998, pp. S40-S44, Vol. 157, No. 2.	
	2.	CHAO, Chia-Lun, et al., "The graded effect of hyperhomocysteinemia on the severity and extent of coronary atherosclerosis", Atherosclerosis, 1999, pp. 379-386, Vol. 147.	
	3.	SPENCE, J. David, et al., "Plasma homocyst(e)ine concentration, but not *MTHFR* genotype, is associated with variation in carotid plaque area", *Stroke*, 1999, pp. 969-973, Vol. 30.	
	4.	VASAN, Ramachandran S., et al., "Plasma homocysteine and risk for congestive heart failure in adults without prior myocardial infraction", JAMA, 2003, pp. 1251-1257, Vol. 289, No. 10.	
	5.	UBBINK, Johan B., et al., " Vitamin requirements for the treatment of hyperhomocysteinemia in humans" Human and Clinical Nutrition, 1994, pp. 1927-1933, Vol. 124.	
	6.	HACKAM, Daniel, G., et al., "What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and below 14 μmol/L", American Journal of Hypertension, 2000, pp.105-110, Vol. 13, No. 1.	
	7.	ANWAR, Wafaa, et al., "Hyperhomocysteinemia is related to residual glomerular filtration and folate, but not to methyleneterahydrofolate-reductase and methionine synthase polymorphisms, in supplemented end-stage renal disease patients undergoing hemodialysis", Clin Chem Lab Med, 2001, pp. 747-752, Vol. 39, No. 8.	
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	14.	VRIESE, An S., et al., " Effect of dialyser membrane pore size on plasma homocysteine levels in haemodialysis patients", Nephrology Dialysis Transplantation, 2003, pp.2596-2600, Vol. 18.	

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	15.	FRIENDMAN, Allon N., et al., " The effect of *N*-acetylcysteine on plasma total homocysteine levels in hemodialysis: a randomized, controlled study", American Journal of Kidney Diseases, 2003, pp. 442-446, Vol. 41, No. 2.	
	16.	VENTURA, Paolo, et al., "Urinary and plasma homocysteine and cysteine levels during prolonged oral N-acetylcysteine therapy", Pharmacology, 2003, pp. 105-114, Vol. 68.	
	17.	LAUTERBURG, Bernhard, et al., " Depletion of total cysteine, glutathione, and homocysteine in plasma by ifosfamide/mesna therapy", Cancer Chemother Pharacol, 1994, pp. 132-136, Vol. 35.	
	18.	PENDYALA, Lakshmi, et al., "Intravenous ifosfamide/mesna is associated with depletion of plasma thiols without depletion of leukocyte glutathione", Roswell Park Cancer Institute, 2000, pp.1314-1321, Vol. 6.	
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	21.	BOSTOM, Andrew G., et al., "Hyperhomocysteinemia and traditional cardiovascular disease risk factors in end-stage renal disease patients on dialysis: a case-control study", Atherosclerosis, 1995, pp. 93-103, Vol. 114.	
	22.	BOSTOM, Andrew G., "Homocysteine: "expensive creatine" or important, modifiable risk factor for arteriosclerotic outcomes in renal transplant recipients?", J Am Soc of Nephrol, 2000, pp. 149-151, Vol. 11.	
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	26.	SOUID, Abdul-Kader, et al., "Blood thiols following amifostine and mesna infusions, a pediatric oncology group study", The American Society for Pharmacology and Experimental Therapeutics, 2001, pp. 1460-1466, Vol. 29.	
	27.	YAMAMOTO, Nobuko, et al., "Effect of cysteine on expression of cystathionine β-synthase in the rat liver", J. Nutr. Sci. Vitaminol., 1995, pp. 197-205, Vol. 41.	
	28.	GOREN, Marshal P., et al., "Reduction of dimesna to mesna by the isolated perfused rat liver", Cancer Research, 1998, pp. 4358-4362, Vol. 58.	

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	29.	FRIEDMAN, Allon N., et al., "Plasma total homocysteine levels among patients undergoing nocturnal *versus* standard hemodialysis", J Am Soc Nephrol, 2002, pp. 265-268, Vol. 13.	
	30.	NYGARD, Ottar, et al., "Plasma homocysteine levels and mortality in patients with cornary artery diease", The New England Journal of Medicine, 1997, pp. 230-236, Vol. 337, No. 4.	
	31.	WALD, David S., et al., "Homocysteine and cardiovascular disease: evidence on causality from a meta-analysis", bmj.com, 2002, pp. 1-7, Vol. 325.	

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